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TITLE: Hyperbaric Oxygen Therapy in the Treatment of Chronic Mild-Moderate Blast-Induced Traumatic Brain Injury PCS and PTSD

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14. ABSTRACT

The purpose of the study is to see if a four-week course of forty low-pressure HBOT's can significantly improve symptoms and cognitive function in military veterans with mild-moderate blast-induced TBI/PCS with PTSD. The scope of the project is to recruit, enroll, treat, and test 50 subjects in a randomized controlled double-blind study within 18 months. There are no results to report at this time since the study has not begun. The study is still in the pre-enrollment regulatory process awaiting a face-to-face meeting with the FDA to discuss IND submission. The author of this report (P.I.) was informed on 11/29/2011 of the date of the meeting which will be 2/13/2012.

15. SUBJECT TERMS
HBOT: hyperbaric oxygen therapy; TBI: traumatic brain injury; PCS: post-concussion syndrome; PTSD: post-traumatic stress disorder

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I. INTRODUCTION

Mild-moderate blast-induced traumatic brain injury (TBI) and post-traumatic stress disorder (PTSD) affect 11-28% and 13-17%, respectively, of U.S. combat troops returning from Iraq and Afghanistan. Evidence-based medicine exists for PTSD, but there is no effective treatment for the post-concussion syndrome (PCS) of mild-moderate TBI nor the combined diagnoses of PCS and PTSD. Between the Fall of 2008 and end of 2010, we conducted a pilot trial of hyperbaric oxygen therapy (HBOT 1.5 atmospheres absolute) in military veterans

with both TBI/PCS and PTSD and achieved substantial symptomatic and cognitive improvements. Preliminary results were published 11/2011 in the Journal of Neurotrauma (http://www.liebertonline.com/doi/abs/10.1089/neu.2011.1895). The purpose of the proposed study is to see if a four-week course of forty low-pressure HBOT's can significantly improve symptoms and cognitive function in military veterans with mild-moderate blast-induced TBI/PCS with PTSD. The scope of the project is to recruit, enroll, treat, and test 50 subjects within 18 months in a randomized controlled double-blind study.

II. BODY

The research accomplishments associated with the tasks in the Statement of Work are as follows:

A. Obtain IRB approval prior to award date: IRB approval was obtained from LSU School of Medicine 12/10/2010. VA IRB approval was not obtained until ORP approval could be secured. Second level ORP approval was held pending FDA IDE procurement. FDA Pre-IDE Request from the fall of 2009 was lost at the FDA. The FDA re-instituted the pre-IDE application in the summer of 2010 and a decision was issued in 5/2011 diverting the P.I. to the FDA Center for Drug Evaluation and Research. The P.I. requested a face-to-face Pre-IND meeting with the FDA that was granted 11/2011. The meeting is scheduled for 2/13/2012.

B. Recruit sufficient numbers of appropriate subjects to complete the study within project period: The study is still in the pre-study regulatory approval process. No recruitment has occurred.

C. Enroll, test, and treat 50 subjects within 17 months from award date: The study is still in the pre-study regulatory approval process. No enrollment has occurred.

D. Analyze data and submit a manuscript for peer-reviewed publication within 24 months of funding: The study is still in the pre-study regulatory approval process. No data has been generated.

III. KEY RESEARCH ACCOMPLISHMENTS

There are no key research accomplishments since the study has not begun.

IV. REPORTABLE OUTCOMES

There are no reportable outcomes since the study has not begun.

V. CONCLUSION

The study is still in the pre-approval regulatory stage awaiting a pre-IND meeting with the FDA. The results of this pre-IND meeting will determine the ability to obtain an IND for the study in its current design or necessitate changes in the study design.

VI. REFERENCES

There are no references.

VII. APPENDICES

There are no appendices.

VIII. SUPPORTING DATA

There is no supporting data.